

REMARKS

Applicant respectfully requests reconsideration of the present application in view of the foregoing amendments and in view of the reasons that follow.

I. Summary of the Claims

Claims 27, 34, 36, 37, 42, and 45 are amended to more clearly and particularly point out Applicant's claimed invention. Claim 44 is requested to be cancelled without prejudice or disclaimer thereof. No claim is newly added.

Applicant respectfully submits that the forgoing amendments do not introduce new matter, and respectfully requests entry thereof by the Examiner. Upon entry of this amendment, claims 27-43 and 45 will remain pending, and claims 27-35, 39-43 and 45 will remain under active consideration.

II. Informalities

The Examiner alleges that claims 27, 42 and 44-45 contain certain informalities. Applicant has amended claims 27, 42 and 44-45 in such a way that resolves the issue.

III. Claim Rejection under 35 U.S.C. § 112, second paragraph

Claim 34 is rejected under 35 U.S.C. §112, second paragraph, for allegedly being indefinite for depending on cancelled claim 1. Applicant has amended claim 34 to depend from independent claim 27, thereby rendering this ground for rejection moot.

Claims 42-45 are rejected under 35 U.S.C. §112, second paragraph, for allegedly being indefinite for alleged lack of sufficient antecedent basis for the recitation of "the target". Applicant has amended claim 42 to provide sufficient antecedent basis for the term "the target," thereby rendering this ground for rejection moot.

Claims 27-35 and 39-41 are rejected under 35 U.S.C. §112, second paragraph, for allegedly being indefinite because "it is unclear whether the recitation of "a microorganism" in step 1) represents the same microorganism recited in the preamble of the claim". Office

Action at 4. Applicant has amended claim 27 to make it clear that the claims refers to a single microorganism, thereby rendering this ground for rejection moot.

IV. Claim Rejections under 35 U.S.C. § 102

A. Rejection under 35 U.S.C. §102(e) over Happe

Claims 42-43 are rejected under 35 U.S.C. §102(e) for allegedly being anticipated by US 2005/0064451 (“Happe”). Applicant respectfully traverses this ground for rejection.

Happe describes a method for detecting bacterial species using PCR. *See* the Abstract of Happe. In sharp contrast, amended claims 42-43 requires the use of a microarray which has attached on its surface at least one nucleic acid probe representing a gene of a eukaryotic cell, and at least one nucleic acid probe representing a gene of a microorganism. Happe fails to disclose at least this feature of the claimed invention. Therefore, Happe cannot anticipate amended claims 42-43.

B. Rejection under 35 U.S.C. §102(b) over Lockhart

Claims 27-28, 39-42 and 44-45 are rejected under 35 U.S.C. §102(b) for allegedly being anticipated by US 6,548,257 (“Lockhart”). Applicant respectfully traverses this ground for rejection.

Lockhart discloses a microarray comprising both eukaryotic gene probes and bacterial gene probes targeting Bio B. *See* Example 1 of Lockhart. However, Lockhart teaches using the disclosed Bio B probes exclusively as a “sample preparation/amplification control”, and not at as a test probe. *Id.* at Table 1; col. 7, lines 59-65; and col. 8, lines 3-5 (“[a]bsolute quantification may be accomplished by inclusion of known concentration(s) of one or more...control nucleic acids such as Bio B”); col. 17, lines 35-51 (“[sample preparation/amplification control probes] are probes that are complementary to subsequences of control genes selected because they do not normally occur in the nucleic acids of the particular biological sample being assayed...[s]uitable sample preparation/amplification control probes include...Bio B”).

In sharp contrast, the claimed methods use the microorganism gene probes as test probes, and require “correlating the selective hybridization [between the sample and the microorganism gene probes] with the presence of a microorganism contamination”. Lockhart fails to disclose as least this feature of the claimed invention. Therefore, Lockhart cannot anticipate claims 27-28, 39-42 and 44-45.

V. Claim Rejection under 35 U.S.C. § 103(a)

Clams 29-35 are rejected under 35 U.S.C. §103(a) for allegedly being unpatentable over Happe in view of Lockhart. Applicant respectfully traverses this ground for rejection.

The problem faced by the present inventor was to develop a method for detecting microorganism contamination in a eukaryotic cell culture and profiling the gene expression of the eukaryotic cells *in a single step*. The present inventor solved this problem by profiling the gene expression of a cell culture using a microarray having both eukaryotic gene probes and contaminating microorganism gene probes. This innovative method makes it possible to not only efficiently detect microorganism contamination, but also to profile gene expression of the eukaryotic cells *in a single step*. Moreover, using Applicant’s claimed method, the impact of contamination on the cultured eukaryotic cells can be easily analyzed by comparing the gene expression profiles of the contaminated cells and the non-contaminated cells.

Neither Happe nor Lockhart discern the technical problem of the claimed invention. Specifically, Happe merely teaches a PCR method for detecting bacteria. This reference does not teach or suggest the concept of simultaneously detecting microorganism contamination and profiling eukaryotic gene expression, *using a single microarray*. Moreover, Lockhart does not teach or suggest the use of a microarray for detecting bacteria. To the contrary, Lockhart specifically directs an ordinary artisan to use bacterial gene probes as controls, *i.e.*, as “sample preparation/amplification control”, and to add “a known amount of the [bacterial] nucleic acids” for purpose of providing “a measure of alteration in the abundance of the nucleic acids caused by processing steps”. Lockhart at Table 1 and col. 17, lines 35-51.

In this regard, Lockhart teaches *away* from using the disclosed Bio B gene probes to detect microorganism contamination in a eukaryotic cell culture. Therefore, one of ordinary

skill in the art looking at Happe and Lockhart would have no motivation to use the Bio B gene probes as contamination markers on a microarray to detect microorganism contamination in cell cultures. Nor would the ordinary artisan be motivated to investigate detecting microorganism contamination and profiling eukaryotic gene expression together using a single microarray, given the disclosure of these two references.

Moreover, Happe teaches nucleic acid sequences for amplifying bacterial 16S rRNA. Happe at Table 1. However, Happe requires the nucleic acid sequences to function as PCR primers. Thus, combining Lockhart's microarray to Happe's bacterial PCR primers would require a change of Happe's principle of operation, in contravene of M.P.E.P. 2143.01 ¶VI ("If the proposed modification or combination of the prior art would change the principle of operation of the prior art invention being modified, then the teachings of the references are not sufficient to render the claims prima facie obvious," citing *In re Ratti*, 270 F.2d 810 (CCPA 1959).).

For at least these reasons, Applicant respectfully submits that the claimed invention is not rendered obvious by the combination of Happe and Lockhart. Withdrawal of the rejection under 35 U.S.C. §103(a) is hereby respectfully requested.

VI. Conclusion

Applicant believes that the present application is now in condition for allowance. Favorable reconsideration of the application as amended is respectfully requested.

The Examiner is invited to contact the undersigned by telephone if it is felt that a telephone interview would advance the prosecution of the present application.

The Commissioner is hereby authorized to charge any additional fees which may be required regarding this application under 37 C.F.R. §§ 1.16-1.17, or credit any overpayment, to Deposit Account No. 19-0741. Should no proper payment be enclosed herewith, as by a check being in the wrong amount, unsigned, post-dated, otherwise improper or informal or even entirely missing or a credit card payment form being unsigned, providing incorrect information resulting in a rejected credit card transaction, or even entirely missing, the

Commissioner is authorized to charge the unpaid amount to Deposit Account No. 19-0741. If any extensions of time are needed for timely acceptance of papers submitted herewith, Applicant hereby petitions for such extension under 37 C.F.R. §1.136 and authorizes payment of any such extensions fees to Deposit Account No. 19-0741.

Respectfully submitted,

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